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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/789,164	02/27/2004	Moon-Hee Sung	P1574	8088

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EXAMINER	
VOGEL, NANCY S	

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 03/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/789,164	SUNG ET AL.	
	Examiner	Art Unit	
	Nancy T. Vogel	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 January 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) *10 and 13-22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9 and 12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2/27/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Attachment: Biol. Deposit*.

DETAILED ACTION

Claims 1-22 are pending in the case.

Receipt of an Information Disclosure Statement on 2/27/04 is acknowledged.

Election/Restrictions

Applicant's election with traverse of Group I, claims in the reply filed on 1/13/06 is acknowledged. The traversal is on the ground(s) that the subject matter of Groups I and II are related since they both recite amphiphilic peptides, i.e P5 and Anal3. This is not found persuasive because each of these peptides has a different and distinct structure and amino acid sequence. While they may share a general property of amphilicity, this does not render the search for the two groups the same. Further, it was clear from the restriction requirement that claims which are included in both groups (claims 1-3) are linking claims which will be examined appropriately (see page 3-4).

The requirement is still deemed proper and is therefore made FINAL.

Claims 10 and13-22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 1/13/06.

Claim Objections

Claims 1, 4, 5, and 11 are objected to because of the following informalities: the term "antibiotics" apparently should read "antibiotic" when appropriate (ie. line 4 of claim

1, line 1 of claim 4, etc.) The verb may have to be changed to agree with the noun. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 4, 6, 8, are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The rejection is based on the Guidelines for the Examination of Patent Applications under the 35 U.S.C. 112, first paragraph "Written Description published in the Federal Register (Volume 66, Number 4, Pages 1099-1111). Claim 1 is drawn to a vector for the surface expression of antibiotics comprising one or more of pgsB, pgsC and pgsA and any gene encoding any amphiphilic antibiotic with antibacterial, antifungal and anticancer activities. Dependent claim 4 recites that the amphiphilic peptide antibiotic "has an identity with" the peptide P5, which is interpreted to mean any amphiphilic peptide with at least one amino acid in common with the peptide P5. Dependent claims recite microorganism transformed with the vector, and pharmaceutical compositions comprising said bacteria. The term "amphiliphilic peptide

antibiotic" is given its broadest reasonable interpretation, which would encompass any peptide having the property of antibacterial, antifungal and anticancer activities. The term "has an identity with" would encompass any peptide having the recited activity and at least one amino acid in common with the peptide to which it is compared, i.e. P5. Claims 1-4, 6, 8 and 11 are genus claims in terms of vectors and cell comprising said vectors comprising any amphiphilic peptide antibiotic with antibacterial, antifungal and anticancer, without structural information other than having at least one amino acid in common with the peptide P5 in some of the claims. Therefore, the claims encompass a broad class of vectors encoding virtually any amphiphilic peptide antibiotic with antibacterial, antifungal and anticancer activities. While the specification provides general information on the amino acid sequence of several amphiphilic peptide antibiotics, including P5, which have the recited activities, there is no structure/function analysis of said antibiotics which would indicate that all peptide antibiotics having the recited activity were adequately described. Therefore, the specification does not describe the claimed vectors comprising amphiphilic peptide antibiotics having antibacterial, antifungal and anticancer activities in such full, clear, concise and exact terms so as to indicate that Applicant has possession of the method at the time of filing the present application. Thus, the written description requirement has not been satisfied.

Claims 5, 7 and 9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which

was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The application discloses E. coli DCTC 10350BP and plasmid pHCE1LB:pgsA-P5 that is encompassed by the definitions for **biological material** set forth in 37 C.F.R. 1.801. Because it is apparent that this biological material is essential for practicing the claimed invention, it must be obtainable by a reproducible method set forth in the specification or otherwise be known and readily available to the public as detailed in 37 C.F.R. 1.801 through 1.809.

It is unclear whether this biological material is known and readily available to the public or that the written instructions are sufficient to reproducibly construct this biological material from starting materials known and readily available to the public. Accordingly, availability of such biological material is deemed necessary to satisfy the enablement provisions of 35 U.S.C. 112. If this biological material is not obtainable or available, the requirements of 35 U.S.C. 112 may be satisfied by a deposit of the biological material. In order for a deposit to meet all criteria set forth in 37 C.F.R. 1.801-1.809, applicants or assignee must provide assurance of compliance with provisions of 37 C.F. R. 1,801-1.809, in the form of a declaration of applicant's representative must provide a statement. The content of such a declaration or statement is suggested by the enclosed attachment. Because such deposit will not have been made prior to the effective filing date of the instant application, applicant is required to submit a verified statement from a person in a position to corroborate the fact, which states that the

biological material which has been deposited is the biological material which has been deposited is the biological material specifically identified in the application as filed (37 C.F.R. 1.804). Such a statement need not be verified if the person is an agent or attorney registered to practice before the Office. Applicant is also reminded that the specification must contain reference to the deposit, including deposit (accession) number, date of deposit, name and address of the depository, and the complete taxonomic description.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-9, 11, 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sung et al. (WO 03/014360 cited by applicants) in view of [amphiphilic peptide antibiotic gene].

Sung et al. disclose vectors for the surface expression of target proteins of interest, comprising one or more than two genes selected from the group consisting of pgsB, pgsC and pgsA, said genes encoding a poly-gamma-glutamate synthetase complex; and a gene encoding a protein of interest, including proteins which are physiologically active substances (see page 1, page 20, lines 5-10, claims). The reference discloses any gram negative or gram positive bacteria comprising said vector (see page 10). Sung et al. disclose the vector pHCE1LB comprising a foreign gene of interest (see Figures). Sung et al. disclose E. coli KCTC10350BP?. Sung et al. disclose lactic acid forming bacteria transformed with said vectors, and pharmaceutical compositions comprising said bacteria (page 67). Sung et al. disclose the usefulness of said system for display on the surface of cells. The difference between the reference and the instant claims is that the reference does not disclose the expression of an amphiphilic peptide antibiotic with antibacterial, antifungal and anticancer activity in the vector and cells.

However, amphiphilic peptide antibiotics having anti-bacterial, anti-fungal and anticancer activity are disclosed by Boman et al. (FEBS Let., 1989, 259, 103) (see abstract, page 104-105). It would have been obvious to one of ordinary skill in the art to have constructed a vector comprising the gene encoding an amphiphilic peptide antibiotic disclosed by Boman et al., with the genes pgsB, pgsC and pgsA, disclosed by

Sung et al., since Boman et al. discloses the usefulness of said amphiphilic peptides and since Sung et al. discloses that any protein of interest may be expressed on the surface of cells using the pgsB, pgsC and pgsA expression system disclosed therein. One of ordinary skill in the art would have been motivated to do so by the benefits disclosed by Sung et al. Based upon the teachings of the cited references, the high skill of one of ordinary skill in the art, and absent evidence to the contrary, there would have been a reasonable expectation of success to result in the claimed invention.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nancy T. Vogel whose telephone number is (571) 272-0780. The examiner can normally be reached on 6:30 - 3:00, Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ntv
3/17/06

NANCY VOGEL
PRIMARY EXAMINER

SUGGESTION FOR DEPOSIT OF BIOLOGICAL MATERIAL ATTACHMENT

A declaration by applicant or assignee, or a statement by applicant's agent identifying a deposit of biological material and averring the following may be sufficient to overcome an objection or rejection based on a lack of availability of biological material. Such a declaration:

1. Identifies declarant.

2. States that a deposit of the material has been made in a depository affording permanence of the deposit and ready accessibility thereto by the public if a patent is granted. The depository is to be identified by name and address. (See 37 C.F.R. § 1.803).

3. States that the deposited material has been accorded a specific (recited) accession number.

4. States that all restrictions on the availability to the public of the material so deposited will be irrevocably removed upon the granting of the patent. (See 37 C.F.R. § 1.808(a)(2)).

5. States that the material has been deposited under conditions that assure that access to the material will be available during the pendency of the patent application to one determined by the Commissioner to be entitled thereto under 37 C.F.R. § 1.14 and 35 U.S.C. § 122. (See 37 C.F.R. § 1.808(a)(1)).

6. States that the deposited material will be maintained with all the care necessary to keep it viable and uncontaminated for a period of at least five years after the most recent request for the furnishing of a sample of the deposited microorganism, and in any case, for a period of at least thirty (30) years after the date of deposit or for the enforceable life of the patent, whichever period is longer. See 37 C.F.R. § 1.806).

7. That he/she declares further that all statements made therein of his/her own knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the instant patent application or any patent issuing thereon.

Alternatively, it may be averred that deposited material has been accepted for deposit under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (e.g., see 961 OG 21, 1977) and that all restrictions on the availability to the public of the material so deposited will be irrevocably removed upon the granting of a patent.

Additionally, the deposit must be referred to in the body of the specification and be identified by deposit (accession) number, date of deposit, name and address of the depository, and the complete taxonomic description.